REMARKS

This paper is responsive to the Office Action mailed September 11, 2007. Claims 1-13, 15-20, 22 and 23 are pending in this application. All claims presently stand rejected.

The present invention is directed to a flexible, kink resistant introducer sheath. A sheath that is flexible and kink resistant can be readily advanced through tortuous body passageways, and directed to target sites deep within the vasculature of a patient. As a sheath is advanced through tortuous body passageways, the sheath should preferably be able to maintain as much of its generally circular cross-section through as large a bending angle as possible. As long as the generally circular cross-section of the sheath remains at least substantially intact, the physician can deliver the largest possible medical interventional device, such as a stent, through the sheath for deployment at the target site.

In the Office Action, claims 1-2, 4, 9-11, 19 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,124 to Horrigan, et al ("Horrigan"). Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 5,380,304 to Parker ("Parker"). Claims 6-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 5,599,325 to Ju, et al. ("Ju"). Claims 12 and 13 were rejected under 35 U.S.C. §103(a) over Horrigan. Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 6,210,396 to MacDonald, et al. ("MacDonald"). Claims 5 and 15-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 6,159,187 to Park et al ("Park"). These rejections will be dealt with in the section of this paper having the heading "Rejections Group 1".

Under what was described by the Examiner in the Office Action as an "alternative interpretation", claims 1-2, 4-5, 10-13, 15-20, 22 and 23 were rejected under 35 U.S.C. §103(a) over Horrigan in view of Park. Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of Park as applied to claim 1, and further in view of Parker. Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju. Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as

applied to claim 1, and further in view of MacDonald[1]. These rejections will be dealt with in the section of this paper having the heading "Rejections Group 2".

Rejections Group 1.

As stated above, claims 1-2, 4, 9-11, 19 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by Horrigan.

As examined herein, claim 1 of the present application was directed to a flexible, kink-resistant introducer sheath including an inner tube extending to a distal end; a wire coil wound around the inner tube extending to an end spaced proximally from the inner tube distal end; a first outer tube disposed around the wire coil and the inner tube therewithin to a first outer tube distal end spaced proximally from the wire coil distal end such that a distal end portion of the wire coil extends distally therebeyond; and at least a second outer tube disposed around the wire coil and the inner tube therewithin extending distally from the first outer tube distal end and covering the distal end portion of the wire coil and extending slightly beyond the distal end of the inner tube. The first outer tube is formed of a material having a relatively hard durometer, and the second outer tube is formed of a material of a substantially softer durometer than the material of the first outer tube.

Horrigan discloses a catheter or sheath having a lubricious inner liner, a wire braid reinforcement, a first outer tube and a second outer tube, wherein the second outer tube is made of softer durometer material than the first outer tube. The wire braid is a 16 strand stainless steel braid. Col. 4, line 23. Horrigan does not teach a coil reinforcement in the claimed sheath, but rather teaches use of a braid reinforcement. In the Office Action, the Examiner contends that a single strand of the 16 strand wire braid meets the limitation of a wire coil in claim 1.

Applicant respectfully takes issue with the Examiner's characterization of a single strand taken from a 16 strand braid as meeting the limitation of a coil. A single strand of wire taken from a woven braid includes, among other things, an undulating or serpentine-type configuration. This configuration results from the interweaving of the numerous wire strands that come together to define the woven braid. The undulating portions are typically present in, or result from, the areas of the wire that are subject to crossover and bending by the various other

[1] Applicant points out that claims 14 and 21 were canceled in Applicant's previous response.

strands that combine to form the braid. Each crossover point creates an undulation, and thereby non-uniform spacing, between adjacent turns of that strand. Having uniform spacing between the coil turns is critical in providing the distribution of bending stress along the length of the sheath. A strand, when isolated from the remainder of the braid, thus includes such undulations which result in non-uniform spacing between the adjacent turns of the strand.

It is well known to those skilled in the art that a coiled reinforcement in a flexible, kink-resistant sheath is structured in a manner such that the spacing is uniform between the individual coil turns. See, e.g., U.S. Patent No. 5,380,304, Col. 4, lines 9-16, and Figs. 2-4. This arrangement is also shown and supported at Figs. 2-4 of the present application. As a result of this construction, the bending and loading stress is distributed along the length of the sheath, without high concentrations of stress at single points. At page 10 of the Office Action, the Examiner pointed out that claim 1 does not recite that the spacing between the coil turns is uniform. Although Applicant respectfully submits that the skilled artisan would interpret the claimed structure to comprise a coil having uniform spacing between individual coil turns in order to achieve the desired kink resistance of the sheath, Applicant has nonetheless amended claims 1 and 22 herein to specify that the spacing between the coil turns is uniform. Horrigan clearly does not teach such structure. Thus, for at least the foregoing reason, Applicant submits that the isolation of a single strand of the 16 strand braid does not meet the limitation of a coil as claimed. As a result claim 1, and all claims depending therefrom, are not anticipated by Horrigan.

In a previous response, Applicant provided case law support for the proposition that even if a single strand from a woven braid can be considered to meet the limitation of a coil (a point that Applicant disputes), the present claims are still not anticipated by the Horrigan reference. In view of the amendment to claim 1 provided herein, it is believed that such support is no longer necessary. If, however, the Examiner still contends that claim 1 is anticipated by Horrigan, reference is respectfully made to the case law cited in the previous response.

Claims 3, 5-8, 12, 13, and 15-18 were rejected as being obvious over Horrigan in view of the secondary references recited above. These claims are dependent, directly or indirectly, on independent claim 1, and include all of its limitations, including the limitation of a coil reinforcement comprising a plurality of uniformly spaced turns. With regard to the secondary

references, Parker was cited in the Office Action for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. Park was cited for its particularized description of a "braided wire coil" and an arcuate coil tip. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1, and that these claims are allowable for at least the same reasons that claim 1 is allowable.

Rejections Group 2.

Under the "alternative interpretation" referred to above, Horrigan was cited by the Examiner as disclosing a sheath having some features in common with the claimed invention, but not teaching the use of a coil as a reinforcement means. Park was cited for teaching a catheter section having a "braided wire coil", with particular reference made to Fig. 7 of Park. Thus, according to the Examiner, it would have been obvious to have substituted a "braided wire coil" as disclosed in Park for the wire braid of Horrigan.

Applicant disputes that such substitution was obvious. In a previous response, Applicant provided the Declaration of Sathya Kaliyamoorthy. Dr. Kaliyamoorthy has a Ph. D in Mechanical Engineering from Case Western Reserve University. Dr. Kaliyamoorthy's Declaration was provided to report and explain the results of a Finite Element Analysis ("FEA") computer simulation test that he carried out to compare the kink resistance of a sheath representative of a braided sheath taught in Horrigan, with the kink resistance of a sheath *otherwise similar to the Horrigan sheath* but having a coil reinforcement instead of the braid reinforcement (Kaliyamoorthy Declaration, paragraph 5). The aim of the test was to establish whether a sheath having a coil reinforcement exhibited greater kink resistance than an otherwise similar sheath having a braid reinforcement.

In the Office Action the Examiner dismissed Dr. Kaliyamoorthy's Declaration because the declaration "...does not state what hardness of PEBAX® was used in the FEA analysis. Declarations comparing applicant's invention/results thereof with those of the prior art must relate to the reference relied upon and the comparison must be with disclosure identical with that of the reference." Office Action, page 10.

Applicant respectfully submits that, to the extent possible due to the limited nature of the disclosure in Horrigan, the FEA simulation was carefully designed to accomplish the very objectives called for by the Examiner. As stated by Dr. Kaliyamoorthy in his declaration,

> 5. I was asked by Cook Incorporated, ("Cook") of Bloomington, Indiana, to examine Cook's United States Patent Application Serial No. 09/815,567 ("the '567 application"), and U.S. Patent No. 5,792,124 to Horrigan, et al., ("Horrigan"). The Horrigan patent was represented to me as being the closest prior art reference cited by the Patent Examiner during prosecution of the '567 application. I was asked to design a computer simulation utilizing Finite Element Analysis ("FEA") to compare the kink resistance of a sheath constructed in accordance with the teachings of the Horrigan patent, to the kink resistance of a sheath <u>otherwise similar to the sheath taught in Horrigan but having a coil reinforcement instead of the braid reinforcement disclosed in Horrigan</u>.
>
> 6. The basic computer simulation model that I constructed for the FEA analysis <u>was designed to be representative of a sheath taught in Horrigan. Another model was designed to be representative of the sheath taught in Horrigan, except that a coil reinforcement was substituted for the braid reinforcement of the Horrigan sheath. Whenever possible, the dimensions of the sheaths utilized for purposes of our FEA analysis were selected to be within a range specifically recited in Horrigan.</u> When a specific dimension for a feature was not explicitly recited in Horrigan, a dimension was selected that was believed appropriate in view of the overall teachings of the Horrigan reference. The specific dimensions used in the FEA were also consistent with physical prototypes used for testing.
> (emphasis not in original declaration)

As further stated by Dr. Kaliyamoorthy, according to his computer simulations, the braid-reinforced sheath representative of the Horrigan sheath quickly began to lose its normalized diameter upon bending, and kinked at a relatively small bending angle of about 21 degrees. At this angle, the normalized stent diameter was reduced to about 0.6, or in other words, the circularity of the sheath was about 60% of normal diameter. Upon further bending, the braid-reinforced sheath lost its entire diameter at a bending angle of about 47 degrees. (Kaliyamoorthy Declaration, paragraph 10.) On the other hand, at the same bending angle of 21 degrees, the coil-reinforced sheath maintained a circularity of about 96%. This coil-reinforced sheath maintained a circularity in excess of 70% of the original diameter until reaching a bending angle of 67 degrees. Thus, it was demonstrated that the coil-reinforced sheath was able to be bent to a

much greater angle (67 degrees vs. 21 degrees) than the braid-reinforced sheath, while maintaining a circularity greater than 70% of its original diameter. (Kaliyamoorthy Declaration, paragraphs 11, 12.)

To place these findings in a real-world context, a stent or other interventional medical device having a diameter approaching that of the normalized diameter of the bent sheath can be passed through the coil-reinforced sheath, until the sheath is bent to an angle of 67 degrees. On the other hand, with a braid-reinforced sheath, the sheath loses much of its normalized stent diameter at a bending angle of only 21 degrees, and loses its entire diameter at 47 degrees. This sheath would have only limited utility for passage of a small diameter stent therethrough once it reaches a bending angle of 21 degrees, and would have no utility for such passage at 47 degrees. Clearly, the FEA test showed that the sheath having a coil reinforcement has utility at bending angles at which the sheath having a braid reinforcement would be unusable. This difference can be critical when attempting to position a medical interventional device, such as a stent, at a branched or otherwise tortuous area of the vasculature. In many such cases, placement utilizing a coil-reinforced sheath would be successful, while an attempted placed with a braid-reinforced sheath would fail.

The Examiner stated that the declaration did not identify a particular hardness of PEBAX® as used in the FEA analysis. Applicant respectfully points out that Table A attached to the declaration specified that the elastic modulus utilized in both models in the FEA analysis was 414 MPa. Elastic modulus is a measure of the stiffness of the material, and a higher elastic modulus translates to a harder material. According to footnote 2 to Table A (attached to the Kaliyamoorthy Declaration), this selected value for the elastic modulus (414 MPa) is a "Typical value for PEBAX® - Reference: Arkema Pebax® 7033 at Matweb." As indicated in the referenced Matweb citation (copy attached hereto as Exhibit A), the Shore D hardness of Arkema PEBAX® 7033 is 70. This representative composition is well within the 65-75D hardness specified in Horrigan (Col. 4, lines 44-45).

Table A also recites additional parameters specifically identified in Horrigan that were utilized in setting up the FEA. As may be noted, Horrigan was silent as to some parameters. As stated in paragraph 6 of the declaration, when a specific dimension for a feature was not

explicitly recited in Horrigan, a dimension was selected that was believed appropriate in view of the overall teachings of the Horrigan reference.

The primary Horrigan reference teaches a guiding catheter for use in PTCA. According to the patent specification, it is an important characteristic of such catheters that they have sufficient stiffness to be pushed through vessels, as well as sufficient rigidity to provide a high degree of torsional control. Col. 1, lines 15-21. This is consistent with the use of a braid-reinforced sheath because a braid-reinforced sheath is generally superior to a coil-reinforced sheath when properties such as stiffness and pushability are of paramount concern. The Horrigan reference neither teaches nor suggests an optimal manner of traversing a tortuous passageway, and in fact, by its use of a braided reinforcement, teaches away from such advantages.

The secondary Park reference teaches a complex solution to the problem of providing access to a target site through increasingly small vessels. The solution to this problem advocated by Park differs considerably from the teachings of the present invention. Park utilizes a catheter having a distal tip section that includes a forming member, such as a woven braid or a coil, formed of a super-elastic material. The forming member is placed in the catheter section and treated in such a way that it has a "second" shape in its equilibrium condition. The forming member is held in a "first", non-equilibrium shape by the presence of an outer polymeric layer. Upon the application of heat to the catheter section in the first shape, the outer restraining layer softens, such that the forming member, and therefore the catheter tip, bends or otherwise assumes the second shape. See, e.g., Col. 8, lines 33-43. Also, compare Figs. 1A and 1B in the Park patent. According to the patent, even though the use of a braid reinforcement may improve the ability of the catheter to transmit torque, at times braiding alone is insufficient. In such cases, "[p]roviding a small amount of shape to the distal section of the catheter can mean the difference between a successful procedure and one that is not as successful." Col. 9, lines 14-17. Thus, Park acknowledges that although the use of a braid improves the ability to transmit torque (a conclusion that is well known to those skilled in the art and, in fact, was previously reported by Applicant herein at paragraph 7 of the Osborne Declaration, filed April 29, 2004), the use of the super-elastic forming member as the braid provides advantages not always attainable with a conventional braid. According to Park, the catheter disclosed therein is superior in certain

instances when compared to a catheter having a conventional reinforcing member.

At page 11 of the Office Action, the Examiner stated that Park et al "teach the substitution of coils for braids (Figs. 7-9) and demonstrate the equivalence of one known type of reinforcement, for e.g. braid, for another, for e.g. coil, to yield predictable results, i.e., controlling the flexibility of an intravascular device, thereby rendering the claimed invention obvious." Applicant disputes that any such conclusion is either taught or suggested in Park. Applicant respectfully submits that in evaluating the scope of the Park disclosure, one must carefully examine the teaching therein. When properly construed, it is apparent that Park makes no claim of equivalence among different types of reinforcements, nor does he even suggest such equivalence. Rather, the teaching in Park is directed to a catheter having a distal tip section that is formable (e.g., bendable) from a first, constrained, shape to a second, equilibrium, shape. The teaching is said to be beneficial when applied to catheters having a braid reinforcement, as well as those having a coil reinforcement. There is no teaching or suggestion of equivalence or interchangeability between such reinforcements, nor is the patent even concerned with making such a conclusion. Applicants respectfully submit that the Examiner is reading too much into Park's statements regarding the breadth of his invention. It is clear that Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a braid, or vice versa, and in fact, provides no reasons why one skilled in the art would ever want to use a coil.

Although Park indicates that his device exhibits (among numerous other cited properties) kink resistance (Col. 2, lines 40-44), this teaching must be read in the context of the invention that he espouses, namely a catheter having a self-formable tip. In fact, in view of Park's stated preference for a braid in his preferred embodiments, one skilled in the art would be led away from the present invention, by erroneously assuming that a braided reinforcement provides better kink resistance than a coil reinforcement. Simply put, Applicant submits that one skilled in the art would not reach the conclusions espoused by the Examiner concerning the alleged equivalency between a braid and a coil upon a review of the Park patent. Reconsideration of this conclusion is respectfully requested.

Therefore, for all of the foregoing reasons, Appellant respectfully submits that claims 1-2, 4-5, 10-13 and 15-20, as amended, are not obvious in view of the cited combination.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US 5,599,325). According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface, and Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

Section 112 rejection.

Claim 22 was rejected under 35 U.S.C. §112, 2nd paragraph, as being indefinite by virtue of the passage "each coil turn being free of interference from another coil turn." Applicant has now amended claim 22 as specified above to remove the objectionable terminology. Based upon the amendment, it is believed that this rejection is now moot.

Conclusion.

Based upon the foregoing, Applicant respectfully submits that all claims 1-13, 15-20 and 22, 23 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,

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EXHIBIT "A"

MatWeb, The Online Materials Database

Arkema Pebax® 7033 SN 01 Polyether Block Amide (PEBA) (Dry)

Subcategory: Elastomer, TPE; Polyether Block Amide (PEBA); Polymer; Thermoplastic

Close Analogs:
Arkema, formed in 2004, was formerly Atofina Chemicals and before that Elf Atochem.

Key Words: Thermoplastic Elastomer, TPE

Material Notes:
POLYETHER BLOCK AMIDE (PEBA) hardness 70 shore D Non plasticized flexible Polyamide Outstanding mechanical properties at low temperature (-40°C) Applications: Sport (Football shoe sole, ski top layer, glasses...) Industrial (conveyor belts, Fasteners...)

ISO data provided by the manufacturer, Arkema.

Physical Properties	Metric	English	Comments
Density	1.02 g/cc	0.0368 lb/in³	
Water Absorption	0.9 %	0.9 %	
Moisture Absorption at Equilibrium	0.6 %	0.6 %	Humidity Absorption
Melt Flow	6 g/10 min	6 g/10 min	235°C/1 kg load
Mechanical Properties			
Hardness, Shore D	70	70	
Tensile Strength, Yield	23 MPa	3340 psi	50 mm/min
Elongation at Break	Min 50 %	Min 50 %	Nominal Strain; 50 mm/min
Elongation at Yield	22 %	22 %	50 mm/min
Tensile Modulus	0.414 GPa	60 ksi	1 mm/min
Charpy Impact Unnotched	NB	NB	
Charpy Impact, Notched, Low Temp	0.55 J/cm²	2.62 ft-lb/in²	at -30°C
Charpy Impact, Unnotched Low Temp	NB	NB	
Charpy Impact, Notched	NB	NB	
Thermal Properties			
Melting Point	172 °C	342 °F	10°C/min
Flammability, UL94	HB	HB	3.1 mm
Flammability, UL94	HB	HB	1.6 mm
Optical Properties			
Transmission, Visible	80 %	80 %	Mfr. reports 'Transparent' but doesn't quantify.